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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Bernhard Brinkhaus

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EXAMINER

WOODALL, NICHOLAS W

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

10/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,606	Applicant(s) BRINKHAUS, BERNHARD	
	Examiner Nicholas Woodall	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5,8 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5,8 and 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 14th, 2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 3-5, 8, and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alby (WO 95/27444) in view of Errico (U.S. Patent 5,725,528) and in view of Altarac (U.S. Publication 2004/0006342).

Alby discloses a device comprising a plate arrangement (7) including a plurality of units including at least one opening (8), a bending zone between each unit, a circular upper disc (6) and a circular lower disc (6) displaceably and rotatably positioned above and below the plate in the opening, wherein the discs include eccentrically disposed holes that receive the bone screw. The bone screw includes a lower shaft part and an upper part screwed into a nut (10) of the plate arrangement. Alby fails to disclose the

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device wherein the bone screw comprises a multi-part screw, the connection of the multi-part screw including a clamping connection, the clamping portion of the connection being located on the upper portion of the screw, the connection of the multi-part screw being positioned within the lower disc, the lower disc being thicker than the upper disc, and the hole of the lower fixation device having a conical shape. Errico teaches a device comprising a multi-part bone screw comprising an upper part (120) having a spherical receptacle (124), wherein the upper part is screwed into a plate arrangement including an opening (164), an upper disc (170), and a lower disc (150), a lower shaft part (100) having a spherical head (108) received within the spherical receptacle in a rotational manner, and a calotte bearing (130) located beneath the spherical receptacle such that the lower shaft part is capable of free movement in a conical manner, wherein the calotte bearing includes a stepped torsion protector, i.e. threads 112 in order to allow the screw to move polyaxially. The examiner would like to note that the specification does not disclose a special definition for the term “calotte” and is therefore interpreting the term “calotte bearing” as a cap including a bearing surface. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Alby further comprising a multi-part screw in view of Errico in order to allow the screw to move polyaxially.

Regarding the connection of the multi-part screw including a clamping connection (claim 14) and the connection of the multi-part screw being positioning within the lower disc (claim 12), Altarac teaches a device comprising a multi-part screw (12 and 20) having a clamping ball and socket connection, wherein the clamping portion

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(26) of the connection is located on the lower portion of the screw , a plate element (40), an upper disc (50), and a lower disc (30), wherein the connection of the multi-part screw is located within the lower disc (see Figure 4) in order to provide the device with a lower profile. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Alby as modified by Errico wherein the connection of the multi-part screw is positioned within the lower disc in view of Altarac in order to provide the device with a lower profile. The device of Alby as modified by Errico disclose a device comprising a multi-part screw including a ball and socket connection (108 and 124) in order to connect the parts of the screw together. Altarac teaches a device comprising a multi-part screw including a clamping ball and socket connection (23 and 26), wherein the clamping portion is located on the lower portion of the screw in order to connect the portions of the screw together. Because both the device of Alby as modified by Errico and the device of Altarac disclose a multi-part screw having a ball and socket connection, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one ball and socket connection for the other in order to achieve the predictable results of connecting the portions of the multi-part screw together.

Regarding the clamping portion of the connection being located on the upper portion of the screw (claim 14), it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Alby as modified by Errico as further modified by Altarac wherein the clamping portion of the connection is located on the upper portion of the screw, since it has been held that a mere reversal

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of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Regarding the opening of the lower disc having a conical shape (claim 12), it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Alby wherein the opening of the lower disc has a conical shape, since the applicant has not disclose the such solves any stated problem or is anything more than one of numerous shapes or configuration a person of ordinary skill in the art would find obvious for the purpose of providing an opening in a lower disc. In re Dailey and Eilers, 149 USPQ 47 (1966).

Regarding the lower disc being thicker than the upper disc (claim 4), since there is no criticality stated in the specification for the lower disk being thicker than the upper disk it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Alby as modified by Errico with the lower disc being thicker than the upper disc, since such a modification would have merely involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Response to Arguments

4. Applicant's arguments filed May 1st, 2009 have been fully considered but they are not persuasive. First the examiner would like to note that the applicant has provided a comparison between the invention as claimed and the device of Alby as modified by Errico in the arguments section of the response including a table highlighting the

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applicant's comparison. The examiner was unable to find any explicitly stated arguments directed to the rejection of the claims, and is using the table of highlighted points as the arguments presented by the applicant. The applicant's argument that the device of Alby as modified by Errico does not provide slots that all continuous sliding of the discs in the longitudinal direction of the plate/rod because the slots include notches to hold the discs is not persuasive. The claim only requires that the discs are located in the plate/rod in a displaceable manner to allow free movement and rotation. Clearly, the Alby reference allows the discs to move and rotate freely within the slots of the plates prior to locking the position of the plate. The claims do not require the discs to have free motion and rotation after tightening/locking the components of the device. The applicant's argument that the device of Alby as modified by Errico does not disclose the screw being capable of continuously sliding in a direction transverse the plate/rod, that the device of Alby as modified by Errico would provide undesired local high pressure between implant parts and in the vertebral column, and that the device of Alby as modified by Errico would require too many instruments to implant are moot, the limitations on which the Applicant relies are not stated in the claims. Therefore, it is irrelevant whether the reference(s) includes those features or not. The applicant's argument that the device of Alby as modified by Errico is too large and too complex for practical use is not persuasive. First, both the Alby reference and the Errico reference are disclosed as being used in the spine and are dimensioned to be used with the spine of a patient. Therefore, one having ordinary skill in the art would know to provide the device of Alby as modified by Errico having a size to fit on the spine of a patient.

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Second, the complexity of the device of Alby as modified by Errico is irrelevant. Many devices used on the spine of a patient are complex. Furthermore, the two arguments appear to be based on bodily incorporation of the Errico teachings to modify the Alby reference. The test for obviousness is not whether the features of one reference may be bodily incorporated into the other to produce the claimed subject matter, but simply what the combination of references makes obvious to one of ordinary skill in the pertinent art. The examiner has provided new grounds of rejection as necessitated by the amendment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
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